

HAND SANITIZER- alcohol gel

Shanghai Hutchison Whitecat Co., Ltd.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Hand Sanitizer

This is a hand sanitizer manufactured according to the Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (CoViD-19); Guidance for Industry.

The hand sanitizer is manufactured using only the following United States Pharmacopoeia (USP) grade ingredients in the preparation of the product (percentage in final product formulation) consistent with World Health Organization (WHO) recommendations:

- a. Alcohol (ethanol) (USP or Food Chemical Codex (FCC) grade) (75%, volume/volume (v/v)) in an aqueous solution denatured according to Alcohol and Tobacco Tax and Trade Bureau regulations in 27 CFR part 20.
- b. WATER
- c. GLYERIN
- d. TROLAMINE
- e. CARBOMER

The firm does not add other active or inactive ingredients. Different or additional ingredients may impact the quality and potency of the product.

Active Ingredient(s)

Alcohol 75% v/v. Purpose: Antiseptic

Purpose

Antiseptic, Hand Sanitizer

Use

Hand Sanitizer to help reduce bacteria that potentially can cause disease. For use when soap and water are not available.

Warnings

For external use only. Flammable. Keep away from heat or flame

Do not use

- in children less than 2 months of age

- on open skin wounds

When using this product keep out of eyes, ears, and mouth. In case of contact with eyes, rinse eyes thoroughly with water.

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Place enough product on hands to cover all surfaces. Rub hands together until dry.
- Supervise children under 6 years of age when using this product to avoid swallowing.

Other information

- Store between 15-30C (59-86F)
- Avoid freezing and excessive heat above 40C (104F)

Inactive ingredients

WATER
GLYERIN
TROLAMINE
CARBOMER

Package Label - Principal Display Panel



WHITECAT[®] Hand Sanitizer

 **Alcohol
Antiseptic
75%**

FRESH COOLING GEL

- ◆ Effectively kills 99.9% of germs
- ◆ Gentle on the skin
- ◆ For topical use only

16.91 FL OZ (500mL)

0570046-1



WHITECAT[®]
Hand Sanitizer

 **Alcohol
Antiseptic
75%**

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol, 75% v/v	Antiseptic
Uses • Hand sanitizer to help reduce bacteria that potentially can cause disease. • For use when soap and water are not available. • Recommended for repeated use.	

Warnings

For external use only. Flammable. Keep away from fire or flame.

Do not use

- ◆ For children less than 2 months of age
- ◆ On open skin wounds

When using this product

- ◆ Keep out of eyes, ears, and mouth
- ◆ In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

- ◆ If lasting irritation or rash occurs.
- ◆ If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- ◆ Place enough product on hands to cover all surfaces. Rub hands together until dry.
- ◆ For children under 6, use only under adult supervision.
- ◆ Avoid direct inhalation of vapors during application. (Headaches and irritation to mucous membranes may occur when directly inhaled.)
- ◆ This product is intended only for hand sanitizing.
- ◆ To prevent drying out and contamination, close the lid completely after use.
- ◆ Keep in their original container not to cause accidents nor diminish the integrity of the product.
- ◆ Do not use over bandages, casting, etc. as irritation may occur.

Other information

• Store below 104 degree F.

Inactive ingredients Water, Glycerin, Carbomer, Triethanolamine.

Shanghai Hutchison Whitecat Co., Ltd.

Shanghai, P.R.C.

www.Whitecat.com

Made in PRC

Distributed by:

22more Limited LLC, Bellevue,

WA 98006

Questions: 833-402-0099

(www.Protectionimports.com)



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77260-201-03

0570046-1



Drug Facts

Active ingredient	Purpose
Ethyl Alcohol, 75% v/v	Antiseptic

Uses • Hand sanitizer to help reduce bacteria that potentially can cause disease. • For use when soap and water are not available.
• Recommended for repeated use.

Warnings

For external use only. Flammable. Keep away from fire or flame.

Do not use

- For children less than 2 months of age
- On open skin wounds

When using this product

- Keep out of eyes, ears, and mouth
- In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

- If lasting irritation or rash occurs.
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Shanghai Hutchison Whitecat Co., Ltd.

Shanghai, P.R.C.

www.Whitecat.com

Made in P.R.C.

Distributed by:

Zzmone Limited LLC, Bellevue,

WA 98006

Questions: 833-402-0099

(www.ProtectionImports.com)



77260-201-04

05700642-1



WHITECAT Hand Sanitizer

 **Alcohol
Antiseptic
75%**

FRESH COOLING GEL

- ◆ Effectively kills 99.9% of germs
- ◆ Gentle on the skin
- ◆ For topical use only

3.38 FL OZ (100mL)

0570054B-1



 **Alcohol
Antiseptic
75%**

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol, 75% v/v	Antiseptic
Uses • Hand sanitizer to help reduce bacteria that potentially can cause disease. • For use when soap and water are not available. • Recommended for repeated use.	

Warnings

For external use only. Flammable. Keep away from fire or flame. Do not use

- For children less than 2 months of age
- On open skin wounds

When using this product

- Keep out of eyes, ears, and mouth
- In case of contact, rinse eyes thoroughly with water.

Stop use and ask a doctor

- If lasting irritation or rash occurs.
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Other information • Store below 104 degree F.

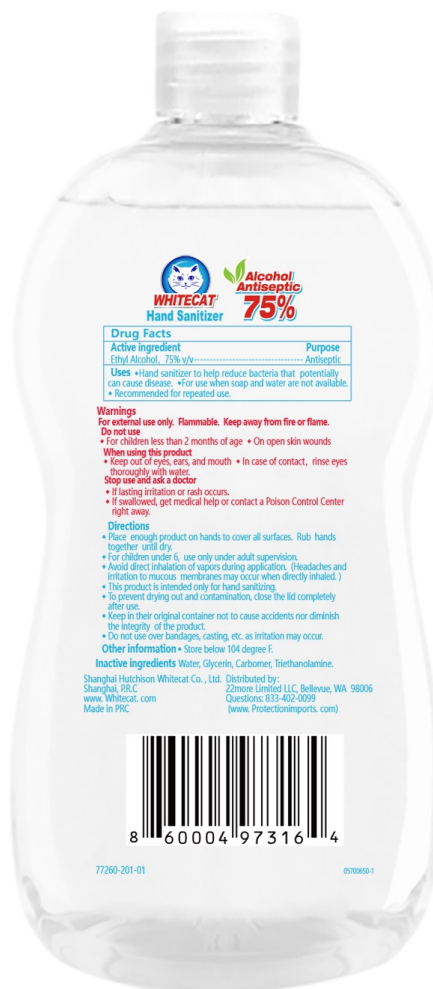
Inactive ingredients Water, Glycerin, Carbomer, Triethanolamine.

Shanghai Hutchison Whitecat Co., Ltd. Distributed by:
Shanghai, P.R.C. 22more Limited LLC, Bellevue, WA 98006
www.Whitecat.com Questions: 833-402-0099
Made in PRC (www.ProtectionImports.com)



77260-201-01

05700550-1



Drug Facts	
Active ingredient	Purpose
Ethyl Alcohol, 75% v/v	Antiseptic
Uses • Hand sanitizer to help reduce bacteria that potentially can cause disease. • For use when soap and water are not available. • Recommended for repeated use.	

Warnings
For external use only. Flammable. Keep away from fire or flame.
Do not use
• For children less than 2 months of age • On open skin wounds
When using this product
• Keep out of eyes, ears, and mouth • In case of contact, rinse eyes thoroughly with water
Stop use and ask a doctor
• If lasting irritation or rash occurs.
• If swallowed, get medical help or contact a Poison Control Center right away.

Directions
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• Do not use over bandages, casting, etc. as irritation may occur.

Other information • Store below 104 degree F.

Inactive ingredients Water, Glycerin, Carboner, Triethanolamine.

Shanghai Hutchison Whitecat Co., Ltd. Distributed by:
Shanghai, P.R.C. Zmore Limited LLC, Bellevue, WA 98006
www.Whitecat.com Questions: 833-402-0009
Made in PRC (www.ProtectionImports.com)



77260-201-01

0570568-1



WHITECAT[®]

Hand Sanitizer

 **Alcohol
Antiseptic**
75%

FRESH COOLING GEL

- ◆ Effectively kills 99.9% of germs
- ◆ Gentle on the skin
- ◆ For topical use only

32.12 FL OZ (950mL)

05700641-1



 **Alcohol
Antiseptic**
75%

Drug Facts

Active ingredient	Purpose
Ethyl Alcohol, 75% v/v	Antiseptic

Uses ♦ Hand sanitizer to help reduce bacteria that potentially can cause disease. ♦ For use when soap and water are not available. ♦ Recommended for repeated use.

Warnings

For external use only. Flammable. Keep away from fire or flame.

Do not use

- ♦ For children less than 2 months of age
- ♦ On open skin wounds

When using this product

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- ♦ Do not use over bandages, casting, etc. as irritation may occur.

Other information ♦ Store below 104 degree F.

Inactive ingredients Water, Glycerin, Carbomer, Triethanolamine.

Shanghai Hutchison Whitecat Co., Ltd.
Shanghai, P.R.C.
www.Whitecat.com
Made in PRC

Distributed by:
22more Limited LLC, Bellevue,
WA 98006
Questions: 833-402-0099
(www.Protectionimports.com)



77260-201-04

05700642-1



HAND SANITIZER

alcohol gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77260-201
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	75 mL in 100 mL

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	

WATER (UNII: 059QF0KO0R)

CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)

TROLAMINE (UNII: 9O3K93S3TK)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77260-201-01	100 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
2	NDC:77260-201-02	450 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
3	NDC:77260-201-03	500 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
4	NDC:77260-201-04	950 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	
5	NDC:77260-201-05	2000 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/30/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	03/30/2020	

Labeler - Shanghai Hutchison Whitecat Co., Ltd. (545844784)

Establishment

Name	Address	ID/FEI	Business Operations
Shanghai Hutchison Whitecat Co., Ltd.		545844784	manufacture(77260-201)

Revised: 4/2021

Shanghai Hutchison Whitecat Co., Ltd.